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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 03 JUN 2005

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Applicant's or agent's file reference JPP279	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/GB2004/002490	International filing date (day/month/year) 14.06.2004	Priority date (day/month/year) 12.06.2003
International Patent Classification (IPC) or national classification and IPC A61M15/00		
Applicant BRITANNIA PHARMACEUTICALS LIMITED et al.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 7 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 06.04.2005	Date of completion of this report 02.06.2005	
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**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/002490

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-29 as originally filed

Claims, Numbers

1-47 received on 11.04.2005 with letter of 06.04.2005

Drawings, Sheets

1/8-8/8 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☒ the claims, Nos. 48
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/002490

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
 - ☒ claims Nos. 47
- because:
- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
 - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☒ no international search report has been established for the said claims Nos. 47
 - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
 - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
 - ☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/002490

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	9,15,21,26,27,29,32,38,42
	No: Claims	1-8,10-14,16-20,22-25,28,30,31,33-37,39-41,43-46
Inventive step (IS)	Yes: Claims	
	No: Claims	1-46
Industrial applicability (IA)	Yes: Claims	1-46
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 47 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT: *a method of dispensing a medicament as an aerosol to a patient*. Consequently, no opinion according to Article 33(1) PCT has been formulated for this claim (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-A-4 114 615 (WETTERLIN KJELL INGVAR LEOPOLD) 19 September 1978
(1978-09-19)

V.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 24 and 29 is not new in the sense of Article 33(2) PCT.

Document **D1**, which is to be regarded as the closest prior art for the present application, discloses:

all features of independent claim 1: a delivery device comprising a housing (Fig.2 (1, 9, 25), a receptacle (Fig.2 (26)) holding a medicament in the form of a powder (column 4, lines 19-21), and a source of propellant (Fig.2 (2)) in form of a canister of gas, whereby the housing provides an inlet for the receptacle and an outlet for the medicament (Fig.2 (22)), wherein the inlet is in fluid communication (Fig.2 (22, 35)) with the source of propellant and is directed against the medicament and the outlet is spaced from the medicament;

all features of independent claim 23: a housing (Fig.2 (1, 9, 25)) having a first and a second open-ended compartment (Fig.2 (1, 25)) wherein the first compartment is adapted to receive a source of a propellant (Fig.2 (2)) in form of a canister of gas and the second compartment is adapted to receive a receptacle (Fig.2 (26)) containing a medicament in powder form wherein the second compartment provides an inlet (Fig.2 (22)) for propellant in fluid communication with the first compartment and an outlet

(Fig.2 (22)) wherein the outlet, in use, is spaced from the medicament;
all features of independent claim 28: a dispensing receptacle (Fig.2 (25)) comprising a receptacle unit (Fig.2 (26)) containing a medicament in powder form which receptacle is in fluid tight engagement with a header unit (Fig.2 - the part comprising the inlet (22), the outlet (22), and the threaded connection for the receptacle (25)) wherein the header unit provides the receptacle with an inlet for propellant (Fig.2 (22)) and an outlet (Fig.2 (22)) wherein the outlet is spaced from the medicament and wherein the header unit has a propellant entry connector (Fig.2 (16)) in fluid communication with the inlet for propellant.

In both devices: the one disclosed by D1 and the other one disclosed by the present application, the source of propellant communicates fluidly with the medicament receptacle in the same way, namely there is present a metering valve in the line connecting the source of propellant and the receptacle:

- in D1 see assembly consisting of one-way valve (16) and metering chamber (17);
- in the present application see the description: page 14, lines 26-29.

V.2 Dependent claims 2-22, 24-27 and 39-46 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step.

All features of dependent claims 2-8, 10-14, 16-20, 22, 24, 25, 30, 31, 33-37, 39-41 and 43-46 are already disclosed in D1, for example:

- decelerating chokes in the propellant pathway (claims 4, 5, 44, 45): Fig.2 (36, 37);
- the outlet flush with the top end of the receptacle (claims 11, 12, 34, 35): Fig.2 (22/25);
- constrictions in the outlet pathway (claims 16, 17, 39, 40): Fig.2 (31);
- a mouthpiece (claims 18, 41): Fig. 2 (23).

The remaining claims (9, 15, 21, 26, 27, 29, 32, 38 and 42) cannot be regarded as involving an inventive step, as they come within the scope of the customary practice followed by persons skilled in the art.

Re Item VII

Certain defects in the international application

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

- VIII.1 The present application contains 47 claims, 3 of which are independent apparatus claims (1, 23, 28) which partly overlap in scope. The excessive number of independent claims and their wording do not allow to clearly delimit the subject matter for which protection is sought so that it is difficult to determine what the invention (if any) should be. Therefore the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT.
- VIII.2 Claim 1 is not clear (Article 6 PCT) - said claim defines a housing providing an inlet and an outlet for the receptacle, whereby it is clear from the description (page 3, lines 13-14), that the housing provides an inlet for the receptacle and an outlet for medicament.

CLAIMS

1. A delivery device for a medicament comprising:
a housing,
5 a receptacle holding a medicament in the form of a powder; and
a source of propellant in the form of a canister of gas,
characterized in that the housing provides an inlet and an outlet for the
receptacle wherein the inlet is in fluid communication with the source of
propellant and is directed against the medicament and the outlet is spaced
10 from the medicament to allow aerosolisation of the medicament.
2. A device according to claim 1 wherein the receptacle is removable
from the housing.
- 15 3. A device according to claim 1 or claim 2 wherein the source of
propellant is removable from the housing.
4. A device according to any one of the preceding claims wherein the
fluid communication between the inlet and the source of propellant is
20 provided by a propellant pathway which has at least one propellant
pathway choke to decelerate the propellant.
5. A device according to claim 4 wherein the propellant pathway
choke is in the form of a constriction or a baffle.
25
6. A device according to any one of the preceding claims wherein the
inlet has an end which is directed against the medicament which is in the
form of a flared tube or of a shower-head.
- 30 7. A device according to any one of the preceding claims wherein the
inlet is in the form of an inlet tube.

8. A device according to claim 7 wherein the tube extends into the receptacle.
9. A device according to claim 7 or claim 8 wherein the tube is provided with one or more perforations.
10. A device according to any one of the preceding claims wherein the receptacle has a bottom containing the medicament and a top which connects to the housing and the outlet is arranged to open into the receptacle at the top of the receptacle.
11. A device according to claim 10 wherein the outlet opens into the receptacle at one end of the outlet which is substantially flush with the top end of the receptacle.
12. A device according to any one of the preceding claims wherein the outlet does not extend into the receptacle.
13. A device according to any one of the preceding claims wherein the outlet is formed as a hole in the housing which is in fluid communication with an outlet pathway in the housing which connects to the exterior of the housing.
14. A device according to any one of the preceding claims wherein a stable aerosol of the medicament is formed upon activation of the device.
15. A device according to claim 14 which has a normally sealed outlet.
16. A device according to any one of claims 1 to 13 wherein the outlet is in fluid communication with an outlet pathway which connects to the exterior of the device wherein the outlet pathway is provided with one or more outlet pathway chokes for decelerating the aerosol of the

medicament

17. A device according to claim 16 wherein the one or more outlet pathway chokes are one or more constrictions and/or one or more baffles.
- 5 18. A device according to any one of the preceding claims which is provided with a mouthpiece attached to the outlet.
- 10 19. A device according to any one of claims 1 to 17 wherein the outlet is provided with a tube for engaging with a breathing tube for a patient using a respirator.
- 15 20. A device according to any one of the preceding claims which is a handheld device.
21. A device according to any one of the preceding claims wherein the canister has a valve and the device is arranged such that in use the valve is above the canister.
- 20 22. A device according to any one of the preceding claims wherein the receptacle is in the form of an open-ended compartment and an optionally removable blister pack.
- 25 23. A housing for a delivery device for a medicament having a first and a second open-ended compartment wherein the first compartment is adapted to receive a source of propellant in the form of a canister of gas and the second compartment is adapted to receive a receptacle containing a medicament in powder form wherein the second compartment provides an inlet for propellant in fluid communication with the first compartment
- 30 and an outlet wherein the outlet, in use, is spaced from the medicament to allow aerosolisation of the medicament.

33

24. A housing according to claim 23 having one or more features as defined in any one of claims 4 to 20.

25. A kit comprising a canister of propellant, a receptacle containing a medicament in powder form and a delivery device housing as defined in claim 23 or 24.

26. A kit according to claim 25 which comprises a plurality of receptacles.

10

27. A kit according to claim 25 or claim 26 wherein the receptacle and source of propellant are provided in the form of combined supply for the first delivery device housing such that the receptacle and source of propellant are linked for combined insertion into the housing.

15

28. A dispensing receptacle comprising a receptacle unit containing a medicament in powder form which receptacle is in fluid tight engagement with a header unit wherein the header unit provides the receptacle with an inlet for propellant and an outlet wherein the outlet is spaced from the medicament to allow aerosolisation of the medicament in use and wherein the header unit has a propellant entry connector in fluid communication with the inlet for propellant.

20

29. A receptacle according to claim 28 wherein the inlet has an end which is directed against the medicament which is in the form of a flared tube or of a shower-head.

25

30. A receptacle according to claim 28 or claim 29 wherein the inlet is in the form of an inlet tube.

30

31. A receptacle according to claim 30 wherein the tube extends into

34

the receptacle unit.

32. A receptacle according to claim 30 or claim 31 wherein the tube is provided with one or more perforations.

5

33. A receptacle according to any one of claims 28 to 32 wherein the receptacle unit has a bottom containing the medicament and a top which connects to the housing and the outlet is arranged to open into the receptacle unit at the top of the receptacle unit.

10

34. A receptacle according to claim 33 wherein the outlet opens into the receptacle unit at one end of the outlet which is substantially flush with the top end of the receptacle unit.

15

35. A receptacle according to any one of claims 28 to 34 wherein the outlet does not extend into the receptacle unit.

20

36. A receptacle according to any one of claims 28 to 35 wherein the outlet is formed as a hole in the header unit which is in fluid communication with an outlet pathway in the header unit which connects to the exterior of the header unit.

25

37. A receptacle according to any one of claims 28 to 36 which is adapted to form a stable aerosol of the medicament in use.

30

38. A receptacle according to claim 37 which has a normally sealed outlet.

39. A receptacle according to any one of claims 28 to 36 wherein the outlet is in fluid communication with an outlet pathway which connects to the exterior of the header unit wherein the outlet pathway is provided with one or more outlet pathway chokes for decelerating the aerosol of

the medicament

40. A receptacle according to claim 39 wherein the one or more outlet pathway chokes are one or more constrictions and/or one or more baffles.

5

41. A receptacle according to any one of claims 28 to 40 which is provided with a mouthpiece attached to the outlet.

10

42. A receptacle according to any one of claims 28 to 40 wherein the outlet is provided with a tube for engaging with a breathing tube for a patient using a respirator.

15

43. A housing for a delivery device for a medicament having a first open-ended compartment which is adapted to receive a source of propellant and a clip which is adapted to receive a dispensing receptacle as defined in any one of claims 27 to 40 wherein the clip is associated with a propellant exit connector in fluid communication with the first compartment which exit connector is arranged to engage with the entry connector of the dispensing receptacle.

20

44. A housing according to claim 43 wherein the fluid communication between the propellant exit connector and the first compartment is provided by a propellant pathway which has at least one propellant pathway choke to decelerate the propellant.

25

45. A housing according to claim 44 wherein the propellant pathway choke is in the form of a constriction or a baffle.

30

46. A kit comprising a source of propellant, a dispensing receptacle according to any one of claims 28 to 42 and a housing according to any one of claims 43 to 45.

47. A method of dispensing a medicament as an aerosol to a patient in need of such treatment which method comprises the steps of:

providing a receptacle having an opening which receptacle contains the medicament in powder form;

5 discharging a pressurised propellant from a canister or cartridge through a delivery tube extending into the receptacle and directed at the medicament so as to fluidise it;

forming an aerosol by transfer of energy from the propellant to the powder; and

10 discharging the aerosol through an outlet passage provided at the opening of the receptacle.

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